

AMENDMENTS TO THE CLAIMS

Listing of Claims:

1. (Original) An oral formulation which includes an intragranular phase comprising a bisphosphonic acid derivative and at least one carbohydrate alcohol, together with an aqueous binder.
2. (Original) A formulation according to claim 1, which does not contain lactose.
3. (Currently Amended) A formulation according to claim 1—~~or 2~~, wherein the bisphosphonic acid derivative is selected from the group consisting of alendronic acid, clodronic acid, ibandronic acid, etidronic acid, pamidronic acid, risedronic acid and tiludronic acid, or a pharmaceutically acceptable derivative, salt, solvate, hydrate, prodrug, enantiomer or racemic mixture thereof.
4. (Currently Amended) A formulation according to ~~any of claims 1 to 3~~ claim 1, wherein the bisphosphonic acid derivative is present in salt form.
5. (Original) A formulation according to claim 4, wherein the bisphosphonic acid derivative is present as a sodium, disodium or trisodium salt, optionally in hydrated form.
6. (Currently Amended) A formulation according to claim 5, wherein the bisphosphonic acid derivative is present as ~~[[the]]~~ a monohydrate, dihydrate or trihydrate.
7. (Currently Amended) A formulation according to claim 5—~~or 6~~, wherein the bisphosphonic acid derivative is selected from the group consisting of alendronate sodium trihydrate, etidronate disodium and risedronate sodium monohydrate.
8. (Original) A formulation according to claim 7, wherein the bisphosphonic acid derivative is alendronate sodium trihydrate.

9. (Original) A formulation according to claim 7, wherein the bisphosphonic acid derivative is etidronate disodium.
10. (Original) A formulation according to claim 7, wherein the bisphosphonic acid derivative is risedronate sodium monohydrate.
11. (Currently Amended) A formulation according to ~~any of claims 1 to 10~~ claim 1, wherein the bisphosphonic acid derivative is present in the range of 0.5% to 40%.
12. (Currently Amended) A formulation according to ~~any of claims 1 to 11~~ claim 1, wherein the carbohydrate alcohol is selected from the group consisting of mannitol, maltitol, sorbitol, lactitol, erythritol and xylitol.
13. (Original) A formulation according to claim 12, wherein the carbohydrate alcohol is mannitol.
14. (Original) An oral formulation which includes an intragranular phase comprising a bisphosphonic acid derivative and a carbohydrate alcohol which is mannitol, together with an aqueous binder.
15. (Currently Amended) A formulation according to ~~any of claims 1 to~~ claim 14, which comprises 15 to 90% of the carbohydrate alcohol.
16. (Original) A formulation according to claim 15, which comprises 15 to 50% of the carbohydrate alcohol.
17. (Original) A formulation according to claim 16, which comprises 15 to 40% of the carbohydrate alcohol.
18. (Currently Amended) A formulation according to ~~any of claims 1 to 17~~ claim 1, wherein the intragranular phase further comprises one or more diluents and / or disintegrants.

19. (Original) A formulation according to claim 18, wherein the diluent is selected from the group consisting of microcrystalline cellulose, powdered cellulose, calcium phosphate-dibasic, calcium sulfate, dextrans, dextrans, alginates and dextrose excipients.

20. (Original) A formulation according to claim 19, wherein the diluent is microcrystalline cellulose.

21. (Currently Amended) A formulation according to claim 19~~-or-20~~, wherein the diluent is present in the range of 15 to 90%.

22. (Original) A formulation according to claim 18, wherein the disintegrant is selected from the group consisting of one or more of low substituted hydroxypropyl cellulose, carboxymethyl cellulose, calcium carboxymethylcellulose, sodium carboxymethyl cellulose, sodium starch glycolate, croscopolone, croscarmellose sodium, starch, crystalline cellulose, hydroxypropyl starch, and partially pregelatinized starch.

23. (Original) A formulation according to claim 22, wherein the disintegrant is sodium starch glycolate.

24. (Currently Amended) A formulation according to claim 22~~-or-23~~, wherein the disintegrant is present in the range of 5 to 20%.

25. (Currently Amended) A formulation according to ~~any of claims 1 to 24~~ claim 1, wherein the binder is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, carboxymethyl cellulose sodium, polyvinylpyrrolidones, starches, gelatins and povidones.

26. (Original) A formulation according to claim 25, wherein the binder is starch.

27. (Currently Amended) A formulation according to claim 25~~-or-26~~, wherein the binder is present in the range of 1 to 15%.

28. (Currently Amended) A formulation according to ~~any of claims 1 to 27~~ claim 1, which further comprises one or more lubricants.

29. (Original) A formulation according to claim 28, wherein said lubricant is selected from the group consisting of talc, magnesium stearate, stearic acid, hydrogenated vegetable oils, glyceryl behenate, polyethylene glycols and derivatives thereof, sodium lauryl sulphate and sodium stearyl fumarate.

30. (Original) A formulation according to claim 29, wherein lubricant is magnesium stearate.

31. (Currently Amended) A formulation according to ~~any of claims 28 to 30~~ claim 28, wherein the lubricant is present in the range of 0.5 to 5%.

32. (Currently Amended) A formulation according to ~~any of claims 1 to 31~~ claim 1, which is a tablet.

33. (Currently Amended) A formulation according to ~~any of claims 1 to 31~~ claim 1, which is a capsule.

34. (New) A formulation according to claim 1 that is substantially free of degradation products associated with the bisphosphonic acid derivative.

~~[[34.]]~~ 35. (Currently Amended) ~~A process of preparing a formulation according to any of claims 1 to 33, which comprises~~ A formulation according to claim 1 prepared by a process comprising intimately mixing a bisphosphonic acid derivative and at least one carbohydrate alcohol to form a dry blend, wet granulating the dry blend with an aqueous binder so as to obtain an intragranular phase, and further formulating the resulting intragranular phase so as to provide the formulation.

~~[[35-51.]]~~ 36-52. (Canceled)